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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,860	04/14/2004	James J. Modliszewski	60307-USA	7246

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EXAMINER	
HELM, CARALYNNE E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,860	MODLISZEWSKI ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-16 and 18-49* is/are pending in the application.

4a) Of the above claim(s) *21-23 and 26-30,* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-16,18-20,24,25 and 31-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/25/08, 3/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refer to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference).

Election/Restrictions

To summarize the current election, applicant elected Group I.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 14-16, 18-20, 24-25, 34-39, 42, and 44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (U.S. Patent No. 6,375,981 – previously cited) in view of Vries (Gums and Stabilisers for the Food Industry 11 2002 pg 201-210 – see IDS) and Van de Velde et al. (Carbohydrate Research 2001 331:271-283 – see IDS).

Gilleland et al. teach a soft capsules made from a soft gel that contain modified starch, hydrocolloid gum and plasticizer, where the film of their invention composes the capsule wall (see abstract and column 2 lines 24-30; instant claims 1, 24, 35, 37, 39, 44, and 47). More specifically, Gilleland et al. teach that the gel composition is prepared with water and has a solids content of 30%-70% by weight (see column 1 lines 60-61, claims 1, 3, and 15 ; instant claims 1, 18-20, 34 and 36). These solids include 25%-75% starch material (bulking agent), 25-75% plasticizer, and 0.1-15% gum (see column 1 lines 62-63, claims 1, 10, and 15; instant claims 1, 3-9, 11 and 34). Based upon these teachings an embodiment exists (at 70% solids, with 15% gum , 15% starch and 70%

plasticizer) where the gum and starch are each present at 10.5% and the plasticizer is present at 49% based on the total weight of the gel (calculated by examiner; see column 1 lines 60-7; instant claims 34 and 35). All the claimed solids and hydrocolloid gum proportions claimed by the instant application are not explicitly taught by Gilleland et al.; however, the breadth of ranges for each that are taught would provide one of ordinary skill in the art at the time of the invention ample reason to further optimize the amounts of each as a matter of routine experimentation and have a reasonable expectation of success for achieving the invention. The gel films and soft capsules are also taught to optionally contain cations that include sodium to enhance the gel strength (see column 4 lines 44-48; instant claim 1). Flavorants and water are also taught as optionally included components in the gel film and soft capsule formulations (see column 4 lines 49-53 and example 8; instant claims 38-39, 42, and 44). Gilleland et al. go on to teach kappa and iota carrageenan, preferably in combination, as hydrocolloid gums that gave good performance in the gel films of their invention (see column 3 lines 33-41, claims 1 and 9). In addition, Gilleland et al. also teach materials to be encapsulated within the soft gel capsule that include pharmaceuticals, nutritional material, and dyes in the list of particularly envisioned items (see column 3 lines 14-16, claims 15 and 18; instant claim 25). Gilleland et al. do not specifically teach the use of kappa-2 carrageenan in their invention.

Vries teaches the properties of kappa, iota, and kappa-2 carrageenan. The teachings of the reference state that molecules of kappa-2 carrageenan actually contain molecules of both kappa and iota carrageenan (see page 202 paragraph 2 lines 4-5 and

table 1). In addition, Vries teaches that kappa-2 carrageenan has properties that are intermediate to both kappa and iota carrageenan, where it has improved strength over iota and improved flexibility over kappa (see table 1). In their discussion of the attributes important in the soft gel films in general, Gilleland et al. teach that flexibility and both dry and wet strength are necessary properties of a film suitable for use (see column 1 lines 23-27). Since Gilleland et al. teach that a mixture of iota and kappa carrageenan produced superior results in their invention it would have been obvious to one of ordinary skill in the art at the time the invention was made to use kappa-2 carrageenan, a mixture at the molecular level of iota and kappa carrageenan, as the hydrocolloid gum in the Gilleland et al. invention (instant claims 34-37).

van de Velde et al. teach characteristics of kappa-iota hybrid carrageenans (kappa-2 carrageenan) (see title). In this discussion, van de Velde et al. teach that kappa-2 carrageenan contains sodium ions (57% and 43% of the total cations) within the length of the molecular chain and give the proportion of this cation relative to others that are present (see table 3 samples CH021 and CH024; instant claim 2). Calcium is one such ion taught to be present at 3% and 5%, respectively (see table 3; instant claims 45-46 and 48). Although van de Velde et al. do not express the presence of these ions relative to the total weight of the kappa-2 carrageenan chain in which they reside, an extreme estimate (e.g. 80%) of the cation composition in the kappa-2 carrageenan indicates that the use of known preparations in the invention of Gilleland et al. in view of Vries would meet the limitations of instant claims 2, 45, and 46. Further, van de Velde et al. draw a distinction between a physical mixture of iota and kappa

carrageenan as opposed to the in-chain mixture (copolymer) of the two in kappa-2 carrageenan. The physical mixture is taught to have the iota and kappa varieties of carrageenan act independently of one another, gelling at different temperatures (see page 280 column 1 paragraph 2). Thus the use of the kappa-2 carrageenan would have the added benefit of conferring properties intermediate to both kappa and iota carrageenan (as taught by Vries) without the two physically separating and acting independently in a composition. In view of these additional teachings it would have further been obvious to one of ordinary skill in the art at the time the invention was made to use kappa-2 carrageenan, instead of a physical mixture of kappa and iota carrageenan, in the film and soft capsules of Gilleland et al.

Explicit teachings are not provided regarding the viscosity of the kappa-2 carrageenan of van de Velde et al. when at 1.5% in a 0.1M sodium chloride solution and measured at 75°C or the break force strength measured in units of grams. Both the break force strength and the viscosity are properties of the chemicals in the composition. The particular break strength of the film produced would be subject to the selection of proportions of components and solids content and thus a matter of routine experimentation for one of ordinary skill to optimize. Further the teachings of the combined references include an embodiment whose constituent proportions mirror that of examples presented by the instant specification. According to MPEP 2112.01, "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." This treatment results from In re Spada, which states

that, "Products of identical chemical composition can not have mutually exclusive properties." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus based on the teachings of the prior art and absent any evidence to the contrary, the claimed viscosity characteristics of kappa-2 carrageenan would be present in the Vries and van de Velde et al. modified Gilleland et al. invention and there would have been a reasonable expectation of success for the combination. Therefore claims 1-11, 14-16, 18-20, 24-25, 34-39, 42, and 44-49 are obvious over Gilleland et al. in view of Vries and van de Velde et al.

Claims 1, 38-40, and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. in view of Vries and van de Velde et al. as applied to claims 1-11, 14-16, 18-20, 24-25, 34-39, 42, and 44-49 above, and further in view of Parikh et al. (U.S. PGPub No. 2004/0013723).

Parikh et al. teach a set of sweeteners (flavorant) useful for inclusion in the soft capsule shells to provide added flavor. Specifically sucrose (sugar) and corn syrup are taught as flavoring agents that can be included in such a configuration (see paragraph 58). It therefore would have been obvious to one of ordinary skill in the art to use the teachings of Parikh et al. to select a particular flavorant to include in the gel film/soft capsule formulation of Gilleland et al. in view of Vries and van de Velde et al. Thus claims 1, 38-40, and 42-44 are obvious over Gilleland et al. in view of Vries, van de Velde et al. and Parikh et al.

Claims 1, 12, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonkwe et al. (U.S. Patent No. 6,949,256) in view of Vries and van de Velde et al.

Fonkwe et al. teach a gel film as well as a soft capsule and solid dosage forms composed of the gel film (see column 3 lines 14-31). The composition is taught to have 11% to 90% solids where iota carrageenan, kappa carrageenan, plasticizer and bulking agent are taught as solids (see column 2 lines 30-45 and column 7 lines 8-12; instant claims 1, 31, and 33). The solid dosage forms are taught to be tablets as well as caplets (synonymous with capsule) (see column 3 lines 28-31 and 56-58; instant claim 32). A particular example has kappa carrageenan, iota carrageenan, modified starch (bulking agent), pregelatinized starch (second film former), and maltitol (plasticizer) (see example 12; instant claim 11). Fonkwe et al. do not teach kappa-2 carrageenan being present in the composition.

As discussed above in the rejection of claims 1-11, 14-16, 18-20, 24-25, 34-39, 42, and 44-49, Vries and van de Velde et al. provide teachings that combined with Fonkwe et al. would make it obvious to one of ordinary skill in the art at the time of the invention to exchange kappa-2 carrageenan in a gel film composition for a physical mixture of iota carrageenan and kappa carrageenan (see ***Claim Rejections - 35 USC § 103*** of claims 1-11, 14-16, 18-20, 24-25, 34-39, 42, and 44-49). Fonkwe et al. in view of Vries and van de Velde et al. teach the film composition with kappa-2 carrageenan at 1%-20%, bulking agent at approximately 2%-86%, plasticizer at 10%-50%, and the balance water (see column 2 lines 30-45). The particular break strength of the film

produced would be subject to the selection of proportions of components and solids content and thus a matter of routine experimentation for one of ordinary skill to optimize. Here again, the teachings of the combined references include an embodiment whose constituent proportions mirror that of examples presented by the instant specification. Since the break force strength is a property of the components used, it is inseparable from these components and one of ordinary skill in the art would have had a reasonable expectation of success for the compositions of Fonkwe et al. in view of Vries and van de Velde et al. to have the claimed break strength force. Therefore claims 1, 12, and 31-33 are obvious over Fonkwe et al. in view of Vries and van de Velde et al.

Claims 1 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Augello et al. (U.S. Patent No. 6,432,448) in view of Vries and van de Velde et al.

Augello et al. teach a gel film composition composed of a strengthening polymer, microcrystalline cellulose, and carrageenan, but in the absence of a plasticizer (column 6 lines 28-36 and 60-63, example 19; instant claims 1 and 41). The tensile, or break force strength of this polymer is taught to be greatly increased by the presence of the strengthening polymer in the composition (see column 6 lines 53-56). Although particular values for the break force strength of the tested films are not explicitly taught by Augello et al. this parameter is inseparably linked to the components used in the composition and as such would be optimized as a matter of routine experimentation by one of ordinary skill in the art. In addition, initial suggestions for the amount solids to be included in the film composition are taught as well. The primary governing factor for this

product parameter is that the hydrated preparation must have a viscosity that is suitable for spraying (see column 8 lines 13-16). Thus this parameter can be optimized by the artisan of ordinary skill and likely achieve the desired level of 50% solids during the course of routine experimentation. Augello et al. do not teach the use of kappa-2 carrageenan as the carrageenan to use or the presence of sodium ions in the composition.

As taught by Vries et al. kappa-2 carrageenan is known to be a gelling variety of carrageenan, and have intermediate characteristics to the two primary gelling carrageenan, kappa and iota, as taught by Augello et al (see Vries table 1 and Augello et al. column 4 lines 35-40; instant claim 1). Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ kapp-2 carrageenan as in the film composition of Augello et al. This modified reference does not speak to the presence of sodium ions in the film composition.

van de Velde et al. teach characteristics of kappa-iota hybrid carrageenans (kappa-2 carrageenan) (see title). In this discussion, van de Velde et al. teach that kappa-2 carrageenan contains sodium ions (57% and 43% of the total cations) within the length of the molecular chain and give the proportion of this cation relative to others that are present (see table 3 samples CH021 and CH024). Therefore the use of such known kappa-2 carrageenans at the time of the invention would also have introduced sodium ions into the composition. Thus claims 1 and 41 are obvious over Augello et al. in view of Vries and van de Velde et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10-12, 18-20, 24-25, and 31-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5, and 8-34 of copending Application No. 10/824688 (referred to as application '688 henceforth).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '688 teach a gel and soft capsule composed of the gel with a second film former, plasticizer and kappa-2 carrageenan that has a viscosity of less than 10 cP at 75°C when measured at 1.5% in a solution of 0.1 molar aqueous sodium chloride. Further, application '688 teaches kappa-2 carrageenan present at 0.5% to 25% based on the total weight of the gel film, a solids

content of at least 50% in the gel, and an encapsulated material. Sodium is also taught present in both the instant gel and soft capsule as well as those of application '688. Although the break force strength of the taught gels is not explicitly taught by application '688, such an attribute is a parameter inseparably linked to the components of the gel. Therefore since the same gel formulations are taught by both the instant claims and those of application '688, they would both also have the same break force strength attributes. Therefore claims 1-8, 10-12, 18-20, 24-25, and 31-33 are obvious over claims 1-2, 5, and 8-34 of copending Application No. 10/824688.

Claims 1, 14-16, 18-20, 24-25, 31-33, 38-39, and 41-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 9-17, 19-21, and 28-31 of copending Application No. 10/824956 (referred to as application '956 henceforth) and claims 1-2, 19-22, 5, 8-17, 19-22, 29, and 34 of copending Application No. 10/824919 (referred to as application '919 henceforth) each in view of van de Velde et al. These two rejections are being handled together since the claims of the two copending applications have very similar language and limitations.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '956 teach a gel film and soft capsule composed of the gel film with plasticizer, flavorant, a second film former and low viscosity guar gum, while the claims of application '919 teach a gel film and soft capsule composed of the gel film with flavorant, plasticizer, a second film former and water

soluble thermoreversible alginate. Further, both applications teach a solids content of at least 50%, particular encapsulated materials, as well as kappa-2 carrageenan as the second film former that is present in the composition. The same break force strengths (all greater than 1500 g) are also taught by the claims of the copending applications and the instant claims. For comparison to the instant application, the alginate and guar gum, for applications '919 and '956 respectively, would serve as the second film former that is present along with kappa-2 carrageenan. Neither application '919 or '956 explicitly teach the presence of sodium in the composition. van de Velde et al. teach characteristics of kappa-iota hybrid carrageenans (kappa-2 carrageenan) (see title). In this discussion, van de Velde et al. teach that kappa-2 carrageenan contains sodium ions (57% and 43% of the total cations) within the length of the molecular chain and give the proportion of this cation relative to others that are present (see table 3 samples CH021 and CH024). Therefore the use of such known kappa-2 carrageenans at the time of the invention would also have introduced sodium ions into the composition. Thus claims 1, 14-16, 18-20, 24-25, 31-33, 38-39, and 41-44 are obvious over claims 1-2, 9-17, 19-21, and 28-31 of copending Application No. 10/824956 and claims 1-2, 19-22, 5, 8-17, 19-22, 29, and 34 of copending Application No. 10/824919 each in view of van de Velde.

Claims 1-12, 14-16, 24, 36-39, and 41-44 are provisionally rejected over claims 1-17, and 23-27 of copending application 10/824793 (referred to as application '793 henceforth) in view of Gilleland et al. and van de Velde et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a delivery system composed of a gel film with a second film former, flavorant, plasticizer and kappa-2 carrageenan. Further, both teach the kappa-2 carrageenan present at 0.5% to 25% based on the total weight of the gel film, a solids content of at least 50% in the gel, a break force strength of at least 1500 g, and an encapsulated material. Copending application '793 does not teach the presence of sodium in the composition nor a soft capsule as their taught delivery system. Gilleland et al. teaches a soft capsule as a delivery system that employs a gel film (see column 2 lines 26-33). Further van de Velde et al. teach characteristics of kappa-iota hybrid carrageenans (kappa-2 carrageenan) (see title). In this discussion, van de Velde et al. teach that kappa-2 carrageenan contains sodium ions (57% and 43% of the total cations) within the length of the molecular chain and give the proportion of this cation relative to others that are present (see table 3 samples CH021 and CH024). Therefore the use of such known kappa-2 carrageenans at the time of the invention would also have introduced sodium ions into the composition. In view of Gilleland et al. it would have been obvious to one ordinary skill in the art at the time the invention was made to select a soft capsule as the particular delivery system of application '793. Therefore claims 1-12, 14-16, 24, 36-39, and 41-44 are obvious over 1-17, and 23-27 of copending application 10/824793 in view of Gilleland et al. and van de Velde.

Claims 1-12, 14-16, 18-20, 24-25, 31-33, 38-39, and 41-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being

unpatentable over claims 1-2, 4-13, 15-16, 21-22, 24-33, 35-36, 40-43, 47, 49, and 52-54 of copending Application No. 11/954958 (referred to as application '958 henceforth) and claims 1-2, 5, 8-11, and 19-20 of copending application No. 12/403993, each separately in view of van de Velde et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each set teaches a gel film and soft capsule composed of the gel film with plasticizer, flavorant, a second film former and kappa-2 carrageenan. Further, both applications teach a solids content of at least 50%, particular encapsulated materials, as break force strengths of greater than 1500 g. Several of the cited claims of application '958 are process claims however, the end result of several of these claims are the products claimed in the instant application. Therefore these process claims make obvious the products they produce. Neither copending application explicitly teaches the presence of sodium in the composition. van de Velde et al. teach characteristics of kappa-iota hybrid carrageenans (kappa-2 carrageenan) (see title). In this discussion, van de Velde et al. teach that kappa-2 carrageenan contains sodium ions (57% and 43% of the total cations) within the length of the molecular chain and give the proportion of this cation relative to others that are present (see table 3 samples CH021 and CH024). Therefore the use of such known kappa-2 carrageenans at the time of the invention would also have introduced sodium ions into the composition. Thus claims 1-12, 14-16, 18-20, 24-25, 31-33, 38-39, and 41-44 are obvious over 1-2, 4-13, 15-16, 21-22, 24-33, 35-36, 40-43, 47, 49, and 52-54 of copending Application No.

11/954958 claims 1-2, 5, 8-11, and 19-20 of copending application No. 12/403993, each separately in view of van de Velde et al.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants' arguments, filed March 30 2009, have been fully considered but they are not deemed to be persuasive.

Applicant argues that there was no suggestion to use kappa-2 carrageenan in place of kappa carrageenan, iota carrageenan or a physical mixture of the two taught by the Gilleland et al. reference. In addition, applicant presents a series of arguments highlighting teachings in several references to support an argument that the use of kappa-2 carrageenan in a gel film would not have been obvious. Gilleland et al. teach gel films composed of kappa carrageenan as well as a physical blend of kappa carrageenan and iota carrageenan (see example 8 and 10). Several drawbacks regarding the use of the kappa carrageenan alone that include rapid thickening with temperature reduction and decrease in flowability with increased solids content are taught (see column 10 lines 35-47). Combination of iota carrageenan with the kappa carrageenan is taught to alleviate these limitations. As applicant, highlights in the arguments, iota and kappa carrageen are natural polymers composed of repeating 3:6-anhydrogalactose subunits where these units are in sulfated form in the iota variant and are non-sulfated in the kappa. Kappa-2 carrageenan is known to be a hybrid or a

copolymer of iota carrageenan and kappa carrageenan, carrying both sulfated and non-sulfated repeat units. As is well known in polymers, both polymer blends and copolymers are utilized in effort to produce a preparation that has properties that are intermediate to the two homopolymers that can be produced from the monomers (see Painter et al. Fundamentals of Polymer Science Lancaster: Technomic Publishing 1994 page 15 paragraph 4). Further, since it was known that 1) kappa-2 carrageenan gels had properties that were intermediate to those of kappa carrageenan and iota carrageenan and 2) kappa-2 carrageenan did not have the undesirable shift in viscosity upon cooling displayed by kappa carrageenan, it would have been obvious for one of ordinary skill in the art to utilize it instead of a physical mixture of iota carrageenan and kappa carrageenan as a known option within their technical grasp (see Vries table 1 and van de Velde et al. figure 5). Applicant points to references that teach the kappa-2 carrageenan as a non-gelling carrageenan variety or a 'weakly gelling' variety having properties distinct from a physical blend. Vries clearly teaches that kappa-2 carrageen forms gels and these gels have properties that are superior to kappa carrageenan although their strength is taught to be less. A relative reduction in strength when considering several variables regarding mechanical properties of the final product (brittleness) and ease of processing (e.g. viscosity and rate of gelation) would not remove the kappa-2 carrageenan from consideration by one of ordinary skill in the art for a gel film material. Although this copolymer may not have the same properties as a physical mixture with the same molar ratio of structural units, this does not preclude the

copolymer from having properties that are intermediate to the two homopolymers and desirable.

Applicant further argues that the references cited in the rejection do not teach a kappa-2 carrageenan with sodium ions and with a break force strength of 1500 g. Gilleland et al. teach the inclusion of various cations in the taught gel film preparation to enhance its strength and viscoelastic properties (see column 4 lines 44-48). Sodium is explicitly named as one envisioned cation (see column 4 line 46). Therefore it would have been obvious to follow this teaching and incorporate sodium ions with the kappa-2 carrageenan whose inclusion was made obvious based on supporting teachings of Vries and van de Velde. The break force strength is a physical property of the gel based upon its chemical constituents. Since a chemical and is properties are inseparable, the gel film resulting from the combination of sodium ions and kappa-2 carrageen would necessarily have the claimed break force strength.

Further arguments presented by applicant regarding rejections based upon the combination of Gilliland et al. with Vries and van de Velde with Parikh as well as Augello et al. or Fonkwe et al. with Vries and van de Velde do not raise any additional issues not already addressed above.

Applicants willingness to file terminal disclaimers as necessary should patentable subject matter be identified is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated

or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615